DEC - 6 2000

K003469

Attachment V

510(k) Summary

Vasomedical, Inc.
EECP® Therapy System Model TS3

1.	Date Prepared:	07 November, 2000
2.	Submitter's Name: and Address	Vasomedical, Inc. 180 Linden Ave. Westbury, NY 11590
3.	Contact Person:	Thomas R. Varricchione, MBA, RRT Vice President, Clinical and Regulatory Affairs Vasomedical, Inc. Telephone: (516) 997-4600 Facsimile: (516) 997-2299 e-mail: tvarricchione@Vasomedical.com
4.	Device Name:	Vasomedical, Inc. EECP® Therapy System Model TS3
	Proprietary Name:	EECP® Therapy System Model TS3
	Common Name:	Enhanced External Counterpulsation (EECP®) Therapy System
	Classification Name:	Device, Counter-pulsating, External
5.	Predicate Device:	The EECP® Therapy System Model TS3 is substantially equivalent to the Enhanced External Counterpulsation Model EECP®-MC2. FDA granted 510(k) clearance for the predicate device on February 23, 1995 (K940264).
6.	Device Description:	The EECP® Therapy System Model TS3 is comprised of three major components, a Control Console, a Treatment Table, and a patient Cuff Set. The Control Console accommodates the air compressor and reservoir, a signal module panel, a power module, a microprocessor with touch screen/keyboard interface, data

storage drives and printer, and components for acquiring and processing ECG and finger plethysmograph signals. The microprocessor is used to operate and monitor the system by means of proprietary custom software, with the operator using the touch screen/keyboard interface to control its operation. The screen displays information pertinent to operating the system, as well as treatment parameters and patient waveforms during use. The touch screen employs "hardware-less keys" which the operator touches to select a function or execute a command and the keyboard enables alphanumeric text entries. An internal hard disk drive is used to store data on the system, an internal floppy disk drive is used to record data onto transferable media, and a printer is used to produce hard copy of site and patient identifiers and physiologic data.

The Treatment Table accommodates a motorized lifting mechanism, mattress and the pneumatic circuit valve assembly. The motorized lifting mechanism is used to move the mattress up and down, providing a convenient height for patient and operator use. The valve assembly consists of three pairs of inflation/deflation valves that open and close on command to inflate or deflate the patient Cuff Set with air. The valve assembly is connected to the air compressor and reservoir components in the Control Console via connecting air hoses.

External pressure is applied via the patient Cuff Set to the lower extremities of the patient in synchronization with the heart, i.e. the cuffs compress vascular beds in the calves, lower thighs and upper thighs/buttocks on inflation. When the heart is in its relaxed state during the diastolic period, pressure is applied sequentially from the calves, to the lower thighs, to the upper thighs and buttocks, forcing blood back to the heart, increasing coronary perfusion pressure and coronary blood flow (diastolic augmentation), as well as venous return. Immediately before the heart begins to eject blood during the next systolic phase, the cuffs are rapidly deflated and all externally applied pressure is eliminated. The vasculature in the lower extremities reconforms and is able to receive the output of the heart with lessened resistance, thereby reducing systolic pressure and the workload of the heart (decreased afterload).

Key differences between the current device and the modified device include:

- A touch screen / keyboard interface has been added to enable the operator to more easily control and monitor operation of the System.
- The display has been modified to allow the operator to simultaneously display ECG, inflation/deflation time, finger plethysmography, heart rate, ratio of pressure amplitudes, ratio of area under pressure waveform and treatment time.
- The valve assembly has been changed to incorporate three sets of computer controlled inflation/deflation rotary butterfly valves with deflation valves normally open so that applied pressure is relieved in the event of arrhythmia or power loss.
- A hand-held stop button has been added to provide easier access to enable the patient to pause the device.

7. Intended Use:

The intended use of the EECP® Therapy System Model TS3 is for the treatment of patients with stable or unstable angina pectoris, acute myocardial infarction, or cardiogenic shock. This is the same Intended Use as the predicate device (Enhanced External Counterpulsation Model EECP®-MC2).

8. Comparison of Technological Characteristics:

Technological and functional characteristics of the modified device are essentially the same as those of the predicate device.

9. Non-clinical Tests:

Non-clinical testing conducted on the EECP® Therapy System Model TS3 included the following:

- Electrical Safety according to methods specified in Standards IEC 601-1.
- Electromagnetic Compatibility according to methods specified in Standards EN 55011/3.1991, Group 1 Class A, IEC 601-1-2. 1993.
- Software verification and validation, as follows:
  - functional requirements as defined in the EECP® Therapy System Model TS3 System Requirements Specification.
  - boundary values and stress testing as defined by FDA's Guidance for the Content of Premarket Submission for Medical Devices Containing Software, CDRH, ODE, FDA, May, 1998.

- safety requirements as identified in the safety risk analysis performed in accordance with EN 1441, Medical Device Risk Analysis, October, 1994, the "Essential Requirements of the Medical Devices Directives", 14 June, 1993, and IEC 601-1-4, Medical Electrical Equipment Part 1: General requirements for safety, 4 Collateral Standard: Programmable electrical medical systems, 1996-05.
- independent testing in support of validation in accordance with the FDA's General Principles of Software Validation, Draft Guidance, June 1997, and IEC 601-1-4, Medical Electrical Equipment Part 1: General requirements for safety, 4 Collateral Standard: Programmable electrical medical systems, 1996-05.

- Verification of System operation, as follows:
  - functional requirements as defined in the EECP® Therapy System Model TS3 System Requirements Specification to verify the performance of the modified device at the system level.
  - safety requirements as identified in the safety risk analysis performed in accordance with EN 1441, Medical Device Risk Analysis.
  - additional verification tests, as indicated, to verify performance at the component level.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2000

Vasomedical, Inc.
c/o Mr. Thomas R. Varricchione, MBA, RRT
Vice President of Clinical and
Regulatory Affairs
180 Linden Avenue
Westbury, NY 11590

Re: K003469
Trade Name: Vasomedical EECP® Therapy System Model TS3
Regulatory Class: III (three)
Product Code: DRN
Dated: November 7, 2000
Received: November 8, 2000

Dear Mr. Varricchione:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Attachment II

Indications for Use Statement

510(k) Number: K003469

Device Name: EECP® Therapy System Model TS3
External Counter-pulsating Device

Indications for Use: Vasomedical, Inc.'s EECP® Therapy System Model TS3 is a non-invasive external counterpulsation device intended for use in the treatment of patients with stable or unstable angina pectoris, acute myocardial infarction, or cardiogenic shock.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K003469

Prescription Use X OR Over-The Counter Use ____
(Per 21 CFR 801.109)